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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**JAZZ PHARMACEUTICALS IRELAND
LIMITED,**

Plaintiff,

v.

TEVA PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

(Filed Electronically)

Plaintiff Jazz Pharmaceuticals Ireland Limited (“Jazz Pharmaceuticals”), by its undersigned attorneys, for its Complaint against Defendant Teva Pharmaceuticals, Inc. (“Teva”), alleges as follows:

Nature of the Action

1. This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, arising from the Defendant’s submission of Abbreviated New Drug Application (“ANDA”) No. 216884 (“Teva’s ANDA”) to the United States Food and Drug Administration (“FDA”) seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of Jazz Pharmaceuticals’s Xywav[®] drug product prior to the expiration of United States Patent Nos. 8,591,922 (“the ’922 patent”); 8,772,306 (“the ’306

patent”); 8,901,173 (“the ’173 patent”); 9,050,302 (“the ’302 patent”); 9,132,107 (“the ’107 patent”); 9,486,426 (“the ’426 patent”); 10,195,168 (“the ’168 patent”); 10,213,400 (“the ’400 patent”); 10,675,258 (“the ’258 patent”); 10,864,181 (“the ’181 patent”); 11,253,494 (“the ’494 patent”); 11,426,373 (“the ’373 patent”); and 11,554,102 (“the ’102 patent”) (collectively, “the patents-in-suit”), which are all owned by Jazz Pharmaceuticals.

The Parties

2. Plaintiff Jazz Pharmaceuticals is a corporation organized and existing under the laws of Ireland, having a principal place of business at Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

3. On information and belief, Defendant Teva is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

The Patents-in-Suit

3. On November 26, 2013, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’922 patent, entitled, “Gamma-hydroxybutyrate compositions and their use for the treatment of disorders.” A copy of the ’922 patent is attached hereto as Exhibit A.

4. On July 8, 2014, the USPTO duly and lawfully issued the ’306 patent, entitled, “Method of administration of gamma hydroxybutyrate with monocarboxylate transporters.” A copy of the ’306 patent is attached hereto as Exhibit B.

5. On December 2, 2014, the USPTO duly and lawfully issued the ’173 patent, entitled, “Gamma-hydroxybutyrate compositions and their use for the treatment of disorders.” A copy of the ’173 patent is attached hereto as Exhibit C.

6. On June 9, 2015, the USPTO duly and lawfully issued the '302 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters." A copy of the '302 patent is attached hereto as Exhibit D.

7. On September 15, 2015, the USPTO duly and lawfully issued the '107 patent, entitled, "Gamma-hydroxybutyrate compositions and their use for the treatment of disorders." A copy of the '107 patent is attached hereto as Exhibit E.

8. On November 8, 2016, the USPTO duly and lawfully issued the '426 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters." A copy of the '426 patent is attached hereto as Exhibit F.

9. On February 5, 2019, the USPTO duly and lawfully issued the '168 patent, entitled, "Gamma-hydroxybutyrate compositions and their uses for the treatment of disorders." A copy of the '168 patent is attached hereto as Exhibit G.

10. On February 26, 2019, the USPTO duly and lawfully issued the '400 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters." A copy of the '400 patent is attached hereto as Exhibit H.

11. On June 9, 2020, the USPTO duly and lawfully issued the '258 patent, entitled, "Method of using gamma-hydroxybutyrate compositions for the treatment of disorders." A copy of the '258 patent is attached hereto as Exhibit I.

12. On December 15, 2020, the USPTO duly and lawfully issued the '181 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters." A copy of the '181 patent is attached hereto as Exhibit J.

13. On February 22, 2022, the USPTO duly and lawfully issued the '494 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters." A copy of the '494 patent is attached hereto as Exhibit K.

14. On August 30, 2022, the USPTO duly and lawfully issued the '373 patent, entitled, "Gamma-hydroxybutyrate compositions and their use for the treatment of disorders." A copy of the '373 patent is attached hereto as Exhibit L.

15. On January 17, 2023, the USPTO duly and lawfully issued the '102 patent, entitled, "Gamma-hydroxybutyrate compositions and their uses for the treatment of disorders." A copy of the '102 patent is attached hereto as Exhibit M.

The Xywav[®] Drug Product

16. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for calcium, magnesium, potassium, and sodium oxybates oral solution (NDA No. 212690), which it sells under the trade name Xywav[®]. The claims of the patent-in-suit cover, *inter alia*, pharmaceutical compositions comprising calcium, magnesium, potassium, and sodium oxybates, and methods of use and administration of pharmaceutical compositions comprising calcium, magnesium, potassium, and sodium oxybates. Jazz Pharmaceuticals owns the patents-in-suit.

17. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Xywav[®].

18. The labeling for Xywav[®] instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Xywav[®] for the treatment of, *inter alia*, cataplexy or excessive daytime sleepiness in patients with narcolepsy.

19. The labeling for Xywav[®] instructs and encourages physicians, pharmacists, other healthcare workers, and patients to modify the dose of Xywav[®] for patients receiving calcium, magnesium, potassium, and sodium oxybates when divalproex sodium (valproate) is concomitantly administered.

20. The labeling for Xywav[®] instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Xywav[®] according to one or more of the methods claimed in the patents-in-suit.

Jurisdiction and Venue

21. This Court has jurisdiction over the subject matter of Counts I through XIII against Teva pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

22. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

23. On information and belief, Teva purposefully has conducted and continues to conduct business in this Judicial District.

24. On information and belief, Teva is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

25. On information and belief, this Judicial District is a likely destination for the generic drug product described in Teva's ANDA.

26. On information and belief, Teva maintains a regular and established, physical place of business in this Judicial District, in at least Parsippany, New Jersey. Teva's website states that its "US Headquarters" is located in Parsippany, New Jersey. *See* <https://www.tevausea.com/contact-us/> (last visited Mar. 21, 2023). In recent court filings, Teva has admitted that it has a "a principal place of business" in Parsippany, New Jersey. *See, e.g.,*

Neurocrine Biosci., Inc. v. Teva Pharm., Inc., et. al., No. 22-965, ECF No. 14 at ¶ 12 (D. Del. Nov. 1, 2022).

27. On information and belief, Teva is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450614134.

28. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

Acts Giving Rise to This Suit

29. Pursuant to Section 505 of the FFDCA, Teva submitted Teva's ANDA seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of calcium, magnesium, potassium, and sodium oxybates oral solution ("Teva's Proposed Product") before the expiration of the patents-in-suit.

30. On information and belief, following FDA approval of Teva's ANDA, Teva will make, use, sell, or offer to sell Teva's Proposed Product throughout the United States, or import such generic product into the United States.

31. On information and belief, in connection with the submission of Teva's ANDA as described above, Teva provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Teva's Paragraph IV Certifications"), alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Teva's ANDA.

32. No earlier than February 6, 2023, Teva sent a written notice of its Paragraph IV Certification to Jazz Pharmaceuticals ("Teva's February 6 Notice Letter"). Teva's February 6 Notice Letter alleged that the claims of the '922, '306, '173, '302, '107, '426, '168, '400, '258, '181, '494, and '373 patents are invalid and/or will not be infringed by the activities described in

Teva's ANDA. Teva's February 6 Notice Letter also informed Jazz Pharmaceuticals that Teva seeks approval to market Teva's Proposed Product before the expiration of the patents-in-suit.

33. No earlier than February 13, 2023, Teva sent a second written notice of its Paragraph IV Certification to Jazz Pharmaceuticals ("Teva's February 13 Notice Letter"). Teva's February 13 Notice Letter alleged that the claims of the '102 patent are invalid and/or will not be infringed by the activities described in Teva's ANDA. Teva's February 13 Notice Letter also informed Jazz Pharmaceuticals that Teva seeks approval to market Teva's Proposed Product before the expiration of the patents-in-suit.

Count I: Infringement of the '922 Patent

34. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

35. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '922 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

36. There is a justiciable controversy between the parties hereto as to the infringement of the '922 patent.

37. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '922 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

38. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '922 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the

United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '922 patent and knowledge that its acts are encouraging infringement.

39. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '922 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '922 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

40. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '922 patent is not enjoined.

41. Jazz Pharmaceuticals does not have an adequate remedy at law.

42. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '306 Patent

43. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

44. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '306 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

45. There is a justiciable controversy between the parties hereto as to the infringement of the '306 patent.

46. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '306 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

47. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '306 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '306 patent and knowledge that its acts are encouraging infringement.

48. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '306 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '306 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

49. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '306 patent is not enjoined.

50. Jazz Pharmaceuticals does not have an adequate remedy at law.

51. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '173 Patent

52. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

53. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '173 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

54. There is a justiciable controversy between the parties hereto as to the infringement of the '173 patent.

55. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '173 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

56. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '173 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '173 patent and knowledge that its acts are encouraging infringement.

57. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '173 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '173 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

58. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '173 patent is not enjoined.

59. Jazz Pharmaceuticals does not have an adequate remedy at law.

60. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '302 Patent

61. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

62. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '302 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

63. There is a justiciable controversy between the parties hereto as to the infringement of the '302 patent.

64. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '302 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

65. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '302 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '302 patent and knowledge that its acts are encouraging infringement.

66. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '302 patent under 35 U.S.C. § 271(c) by

making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '302 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

67. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '302 patent is not enjoined.

68. Jazz Pharmaceuticals does not have an adequate remedy at law.

69. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '107 Patent

70. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

71. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '107 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

72. There is a justiciable controversy between the parties hereto as to the infringement of the '107 patent.

73. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '107 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

74. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '107 patent under 35 U.S.C. § 271(b) by

making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '107 patent and knowledge that its acts are encouraging infringement.

75. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '107 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '107 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

76. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '107 patent is not enjoined.

77. Jazz Pharmaceuticals does not have an adequate remedy at law.

78. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '426 Patent

79. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

80. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '426 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

81. There is a justiciable controversy between the parties hereto as to the infringement of the '426 patent.

82. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '426 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

83. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '426 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '426 patent and knowledge that its acts are encouraging infringement.

84. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '426 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '426 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

85. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '426 patent is not enjoined.

86. Jazz Pharmaceuticals does not have an adequate remedy at law.

87. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '168 Patent

88. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

89. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '168 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

90. There is a justiciable controversy between the parties hereto as to the infringement of the '168 patent.

91. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '168 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

92. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '168 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '168 patent and knowledge that its acts are encouraging infringement.

93. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '168 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that

Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '168 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

94. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '168 patent is not enjoined.

95. Jazz Pharmaceuticals does not have an adequate remedy at law.

96. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '400 Patent

97. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

98. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '400 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

99. There is a justiciable controversy between the parties hereto as to the infringement of the '400 patent.

100. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '400 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

101. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '400 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will

intentionally encourage acts of direct infringement with knowledge of the '400 patent and knowledge that its acts are encouraging infringement.

102. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '400 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '400 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

103. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '400 patent is not enjoined.

104. Jazz Pharmaceuticals does not have an adequate remedy at law.

105. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX: Infringement of the '258 Patent

106. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

107. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '258 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

108. There is a justiciable controversy between the parties hereto as to the infringement of the '258 patent.

109. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '258 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

110. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '258 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '258 patent and knowledge that its acts are encouraging infringement.

111. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '258 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '258 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

112. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '258 patent is not enjoined.

113. Jazz Pharmaceuticals does not have an adequate remedy at law.

114. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count X: Infringement of the '181 Patent

115. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

116. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '181 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

117. There is a justiciable controversy between the parties hereto as to the infringement of the '181 patent.

118. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '181 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

119. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '181 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '181 patent and knowledge that its acts are encouraging infringement.

120. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '181 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '181 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

121. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '181 patent is not enjoined.

122. Jazz Pharmaceuticals does not have an adequate remedy at law.

123. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XI: Infringement of the '494 Patent

124. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

125. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '494 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

126. There is a justiciable controversy between the parties hereto as to the infringement of the '494 patent.

127. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '494 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

128. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '494 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '494 patent and knowledge that its acts are encouraging infringement.

129. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '494 patent under 35 U.S.C. § 271(c) by

making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '494 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

130. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '494 patent is not enjoined.

131. Jazz Pharmaceuticals does not have an adequate remedy at law.

132. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XII: Infringement of the '373 Patent

133. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

134. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '373 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

135. There is a justiciable controversy between the parties hereto as to the infringement of the '373 patent.

136. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '373 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

137. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '373 patent under 35 U.S.C. § 271(b) by

making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '373 patent and knowledge that its acts are encouraging infringement.

138. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '373 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '373 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

139. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '373 patent is not enjoined.

140. Jazz Pharmaceuticals does not have an adequate remedy at law.

141. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIII: Infringement of the '102 Patent

142. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

143. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '102 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

144. There is a justiciable controversy between the parties hereto as to the infringement of the '102 patent.

145. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '102 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

146. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '102 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '102 patent and knowledge that its acts are encouraging infringement.

147. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '102 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '102 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

148. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '102 patent is not enjoined.

149. Jazz Pharmaceuticals does not have an adequate remedy at law.

150. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Jazz Pharmaceuticals respectfully requests the following relief:

(A) A Judgment that Teva has infringed the patents-in-suit by submitting ANDA No. 216884;

(B) A Judgment that Teva has infringed, and that Teva's making, using, selling, offering to sell, or importing Teva's Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 216884 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Teva and its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Teva's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from practicing any compositions or methods claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, offer for sale, or sale in, and/or importation into, the United States of Teva's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Teva, its officers, agents, attorneys, and/or employees, or those acting in privity and/or concert with them, have committed any acts with respect to the compositions or methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Jazz Pharmaceuticals damages for such acts;

(H) If Teva, its officers, agents, attorneys, and/or employees, or those acting in privity and/or concert with them, engages in the commercial manufacture, use, offer for sale, or sale in, and/or importation into, the United States of Teva's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Jazz Pharmaceuticals resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Jazz Pharmaceuticals its attorneys' fees incurred in this action;

(K) A Judgment awarding Jazz Pharmaceuticals its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: March 21, 2023

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter captioned *Jazz Pharmaceuticals Ireland Limited v. Lupin Inc., et al.*, No. 21-14271 (SRC)(JSA) (D.N.J.) (consolidated) is related to the matter in controversy because the matter in controversy involves the same plaintiff and the same patents, and because Teva is seeking FDA approval to market generic versions of the same pharmaceutical product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: March 21, 2023

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